REMARKS

This is in response to the final Office Action dated 3/30/2011.

Claims 35-46 and 48 are pending. Claims 1-34, and 47 are canceled.

A Request for Continued Examination is submitted herewith.

Reconsideration of the application in view of the following is requested.

Claims 35-46 and 48 stand rejected under 35 USC § 103(a) as being unpatentable over Tomai (US 20030133913) in view of Allen (US 6334856) and Babiuk (Journal of Controlled Release, 66, 2000).

While Applicants respectfully traverse the asserted prima facie obviousness position for the reasons presented in the prior response filed 1/12/11, it is also requested that the Examiner further consider the application in view of data showing that TLR 7 and/or 8 agonist IRM compounds of the type set forth in the present claims provide unexpected results. As an example, a TLR 8 agonist thiazoloquinoline amine known as 3M R-853 has shown a dramatic increase in effectiveness when delivered coated on solid microneedles (sMTS).

Below is a summary of data for a vaccine study in hairless guinea pigs (HGP), which utilized R-853 as an adjuvant for tetanus toxoid (TT) that was delivered via sMTS vs. intramuscular (IM) and sMTS without R-853.

Dose of Tetanus Toxoid	Dose of R-853	Delivery Method	number of HGP	mean titer of anti-TT antibody at 8 wk (4 wk post boost)
1.0 mcg	0 mcg	IM	5	257
1.1 mcg	0 mcg	sMTS	5	319
1.0 mcg	10.1 mcg	sMTS	5	659
5.0 mcg	0 mcg	IM	5	696
4.1 mcg	0 mcg	sMTS	5	714
5.2 mcg	12.1 mcg	sMTS	5	1421

It can be seen the antibody titers are much higher for the combination of R-853 and tetanus toxoid coated on microneedles compared to intramuscular delivery or microneedle delivery of tetanus toxoid vaccine alone.

This substantial improvement would not have been predictable based on the cited references. Accordingly, it is submitted that the claims are patentable and withdrawal of the rejection is requested.

Claims 35-46 and 48 also stand rejected under 35 USC § 103(a) as being unpatentable over Thomsen (WO02/24225 A1) in view of Allen (US 6334856).

Applicants respectfully traverse.

While Thomsen discloses use of certain imidazoquinoline amines as adjuvants for DNA vaccines, there is nothing to suggest delivery using microneedles or the surprising results set forth above by the data using R-853. At the time of the invention there was no way to predict how the claimed TLR 7 and/or 8 IRM compounds would behave when delivered via microneedles. Accordingly, it is submitted that the claims would not have been obvious and the surprising results would not have been predictable based on Thomsen in view of Allen.

Finally, a provisional obviousness-type double patenting rejection was made based on claims 16-59 of application 10/925473 in view of Allen. Since the rejection is provisional, Applicants request to wait until allowable subject matter is indicated in one of the two applications in order assess whether to file a terminal disclaimer at that time.

In view of the above, it is submitted that the application is in condition for allowance. Reconsideration and favorable action are therefore requested.

Respectfully submitted,

December 30, 2011
Date

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